IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF HAWAII

STATE OF HAWAII ex rel. LISA TORRICER; UNITED STATES OF AMERICA ex rel. LISA TORRICER, Plaintiffs, vs. LIBERTY DIALYSIS-HAWAII LLC; LIBERTY DIALYSIS-NORTH HAWAII LLC; AND FRESENIUS MEDICAL CARE HOLDINGS, INC., Defendants.	Civ. No. 19-00101 JMS-RT ORDER GRANTING DEFENDANTS' MOTION TO DISMISS, ECF NO. 58

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I. INTRODUCTION

Defendants Liberty Dialysis-Hawaii LLC, Liberty Dialysis-North Hawaii LLC, and Fresenius Medical Care Holdings, Inc. (collectively, "Liberty" or "Defendants") move the dismiss the First Amended Complaint ("FAC") filed by Relator Lisa Torricer ("Relator") in this *qui tam* action. Relator brought the action on behalf of the State of Hawaii under the Hawaii False Claims Act (the "Hawaii FCA"), Hawaii Revised Statutes ("HRS") § 661-25; and on behalf of the United

States under the federal False Claims Act (the "FCA"), 31 U.S.C. § 3730(b).[1]

The FAC alleges that, since at least March 2013, Liberty submitted Medicare and Medicaid claims for payment for end-stage renal disease ("ESRD") services even though Liberty had faulty plans of care ("POCs"), and other deficiencies, in violation of Medicare regulations set forth in 42 C.F.R. Part 494 ("Conditions for Coverage for [ESRD] Facilities") and related regulations. Relator alleges that Liberty backdated and falsely completed POC forms by inserting signatures and stability determinations after the fact, and in some cases, submitted claims without documented POCs at all. She contends that, after becoming aware of these deficiencies, Liberty became obligated to return Medicare and Medicaid payments, and concealed the scope of its deficiencies to avoid having to return such overpayments. *See generally* ECF No. 51 at PageID ## 602-08.

Nevertheless, even assuming at this motion-to-dismiss stage that the allegations of fraud are true, the court concludes after considerable research and review of supplemental briefing that Relator fails to state valid claims for relief. The FCA "is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Universal Health*

[1] Under § 3730(b), "a private person, known as a relator, may bring a *qui tam* civil action 'for the person and for the United States Government' against the alleged false claimant, 'in the name of the Government.'" *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1510 (2019) (quoting § 3730(b)).

Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2003 (2016) ("*Escobar*") (internal citation omitted). It only imposes liability for a materially false or fraudulent "claim for payment or approval." 31 U.S.C. § 3729(a)(1). Because such claims are not implicated here, the court GRANTS Defendants' Motion to Dismiss with prejudice.

II. BACKGROUND

A. Factual Background

As alleged in the FAC, Liberty Dialysis-Hawaii LLC, Liberty Dialysis-North Hawaii LLC ("Liberty North"), and Fresenius Medical Care Holdings, Inc. ("Fresenius") "jointly own, operate and manage 19 dialysis clinics caring for over 2,000 patients across the State of Hawaii, including but not limited to Defendants' Siemsen, Sullivan and Home Program Units." ECF No. 51 at PageID # 610. Approximately 80 percent of Liberty Dialysis-Hawaii and Liberty North's patients were covered by Medicare and/or Medicaid during relevant time periods. *Id.* at PageID # 614-15.[2] "In or about 2011, Liberty Dialysis[-]Hawaii and Liberty Dialysis North Hawaii merged with and/or [were] was acquired by Fresenius after Medicare switched to a bundled payment system for ESRD

[2] Under 42 U.S.C. § 1395rr, both Medicare and Medicaid provide some portion of payment for benefits for ESRD treatment and services for eligible persons.

treatment. As a result, Fresenius owns, operates and/or manages all Liberty and Liberty North dialysis clinics." *Id.* at PageID # 615.

In March of 2013, Relator worked for Liberty as a "Social Worker Assistant tracking [POCs]." *Id.* at PageID # 608. Previously, she worked for Liberty as a hemodialysis technician but was placed on "light duty" after an injury in 2010. *Id.* at PageID # 633. "In early 2012, her light duty included monitoring the [POC] process at Defendants' Siemsen and Sullivan clinics" and "also included generating missing flow sheets and tracking [POCs] for Home Programs patients." *Id.*

POCs are developed as part of several "conditions for coverage" set forth in 42 C.F.R. Part 494. Under 42 C.F.R. § 413.210(a) (titled "Conditions for payment under the [ESRD] prospective payment system"), "[t]o qualify for payment, ESRD facilities must meet the conditions for coverage in part 494 of this chapter." In particular, 42 C.F.R. § 494.90 provides, in part, that an "interdisciplinary team" consisting of a nurse, physician, social worker, and dietician "must develop and implement" a POC that specifies needed services. *See also* 42 C.F.R. § 494.80 (defining members of the interdisciplinary team). Under § 494.90(b), the completed POC must "be signed by team members, including the

patient . . . or, if the patient chooses not to sign the [POC], this choice must be documented on the [POC], along with the reason the signature was not provided."[3]

The FAC also highlights other conditions for coverage in Part 494, including sections requiring compliance with applicable laws and regulations (§ 494.20); patient assessments, including periodic assessments of a patient's stability (§ 494.80(d)); home care conditions (§ 494.100); and medical records (§ 494.170). *See* ECF No. 51 at PageID ## 621-27.

Relator alleges that, as part of her duties, focusing on records from 2012 and 2013 at "Siemen, Sullivan, and Home Programs," she documented whether components of POCs had been completed, were not timely completed, or were never completed. *Id.* at PageID # 634. She noted entries where POCs sometimes were printed or faxed for physicians' signatures after their due dates, indicating that physicians' signatures were "manually added" after the fact. *Id.* at PageID # 635.

On March 7, 2013, the Hawaii Department of Health's Office of Health Care Assurance ("OHCA") conducted an annual Medicare certification survey to assess compliance with Part 494's conditions for coverage. *Id.* at PageID

[3] Part 494 and related regulations are discussed in more detail later in this Order when assessing whether the regulations are "material" for purposes of liability under the FCA.

636. OHCA discovered that some patients did not have current POCs, and cited Defendants for noncompliance with § 494.90. *Id.* at PageID # 636-37. OHCA then "ordered the Siemsen unit to self-audit all [POCs]." *Id.* at PageID # 640.

As a result, a Liberty nurse manager "ordered the unit clerks to backdate ESRD Team members' signatures on [POCs] that had been signed but left undated," *id.* at PageID # 637, and "to mark patients' status on [POCs] as 'stable' or 'unstable' if a stability determination had not been made." *Id.* at PageID # 636-37. "Relator learned from direct review of patient records and conversations with other employees that Team members had been backdating medical records for years to conceal noncompliance." *Id.* at PageID # 638. The nurse manager "warned Relator that the Government would terminate Medicare certification if it learned the severity of Defendants' noncompliance. She also told Relator that they would not report the noncompliance she uncovered because it would jeopardize certification and require them to return Government overpayments." *Id.* at PageID # 639. The FAC alleges that after a clerk told a manager that she "was uncomfortable making stability determinations," the nurse manager told her that "backdating signatures and making stability determinations after-the-fact did not constitute falsifying medical records." *Id.*

Relator alleges that, as part of the audit, she was "ordered . . . to backdate Team members' [POC] acceptance signatures to make the records 'compliant.'" *Id.* at PageID # 641. She was ordered "to falsify records to retain Medicare certification and Government overpayments." *Id.* at PageID # 642. Relator alleges that when she "could not bring herself to backdate signatures or attempt to make stability determinations," she was told to use "the date the last Team member signed." *Id.* She was again told that "there was nothing wrong with backdating [POCs]." *Id.* at PageID # 643. And so Relator "researched the applicable regulations herself . . . and learned that Defendants were required to abide by the conditions of coverage set forth in 42 C.F.R. [P]art 494 to qualify for Government reimbursement." *Id.*

Relator "maintained personal work journals at her desk to document deficiencies," and recorded numerous deficiencies in initial POCs, three-month POCs, and annual POCs for "Siemsen/Sullivan patients," all with missing components or signatures. *Id.* at PageID ## 644-45. On March 26, 2013, Relator called her union representative to express concerns. *Id.* at PageID # 647. She also "contacted someone at a federal agency" (an agency "that fielded calls regarding Medicare fraud, waste, and abuse"), and the Fresenius compliance hotline on March 28, 2013. *Id.* Nothing resulted from those complaints.

In April 2013, Relator began working on a similar audit for Home Programs, and notified her supervisor about similar POC problems with those programs. *Id.* at PageID # 649. She discovered that many of the Home Program POCs were not completed timely, were missing required entries, and lacked signatures. *Id.* at PageID ## 650-51. Many were missing required "flowsheets." *Id.* at PageID ## 651-52. "By ordering Relator and other employees and RNs to obtain necessary information and signatures on a backlog of flow sheets, some nearly a year old, [Liberty] attempted to 'correct' past noncompliance." *Id.* at PageID # 652. The FAC alleges that "Defendants' various attempts to conceal noncompliance," made it "difficult if not impossible, for the Government to discover millions of dollars of overpayments it made for patients' thrice-weekly treatments going back at least as far as 2011." *Id.* at PageID # 652.

Relator claims that in June 2013 she discovered her work journals were missing, implying that someone affiliated with Liberty is responsible for confiscating them. *Id.* at PageID ## 652-53. She alleges that she has been on workers' compensation leave since August 2013, after having been told on August 15, 2013 that Liberty "no longer had light duty work for her." *Id.* at PageID # 660-01.

The FAC gives a detailed example of a deficient POC, which depicts a POC with blank dates next to some signatures, and a missing physician signature, although it lists the patient as being "stable." *Id.* at PageID # 657. Relator alleges that she was told in 2018 by an employee that "Defendants' noncompliance with the [POC] requirements is ongoing," and that therefore "Defendants remain Medicare-certified by not reporting noncompliance and by backdating records to make noncompliance difficult to detect." *Id.* at PageID # 663.

B. Procedural Background

Relator filed a prior FCA action in this court on August 7, 2015, based on the same basic allegations as in this case, using her then-married name, Lisa Cabico. *See United States ex rel. Cabico v. Liberty Dialysis-Hawaii LLC et al.*, Civ. No. 15-00309 JMS-RLP (D. Haw.). It was filed under seal as required under 31 U.S.C. § 3730(b)(1). After the United States declined to intervene, the *Cabico* complaint was unsealed on October 24, 2016. *See* ECF No. 51 at PageID # 609. Relator later filed a notice of dismissal of that action without prejudice on May 23, 2017. *Id.*; Civ. No. 15-00309 JMS-RLP, ECF No. 25.

On February 1, 2019, Relator filed the present action (using her maiden name, Lisa Torricer) in the Circuit Court of the First Circuit, State of Hawaii. ECF No. 1-1. The action was brought on behalf of both the State of

Hawaii and the United States of America under the Hawaii FCA and the federal FCA. *Id.* at PageID ##11-12. On March 1, 2019, the United States removed the action to this court under the Federal Officer Removal Statute, 28 U.S.C. § 1442(a)(1).[4] ECF No. 1 at PageID # 3. On April 23, 2019, the State of Hawaii declined to intervene. ECF No. 11. On July 8, 2019, the United States gave notice that it again declined to intervene, ECF No. 17, and the action was unsealed on July 9, 2019. ECF No. 19. After counsel withdrew from representing her, Relator was given time to secure new counsel, ECF No. 30, and her current counsel entered appearances on December 27, 2019, ECF No. 33, and March 13, 2020, ECF No. 37.

On June 4, 2020, Relator filed the FAC. ECF No. 51. The FAC alleges the following eight Counts:

[4] Generally, only defendants may remove to federal court an action pending in state court. *See* 28 U.S.C. § 1441(a) ("Except as otherwise expressly provided by an Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending."). Because the United States is not a defendant in this action, the precise basis of the United States' removal here is unclear, although § 1442(a)(1) states in part that "[a] civil action . . . that is commenced in a State court and that is against *or directed to* any of the following may be removed by them to the district court . . . (1) The United States or any agency thereof . . ." (emphasis added). This *qui tam* action might be construed as being "directed to" the United States even if it is not *against* the United States. The court, however, need not address this question further because no party sought to remand this case within 30 days of removal, *see* 28 U.S.C. § 1446(a), and the court clearly has subject matter jurisdiction based upon alleged violations of the FCA.

- Count One: False Claims in Violation of the Hawaii FCA, HRS § 661-21(a)(1);
- Count Two: False Records or Statements Material to False Claims in Violation of the Hawaii FCA, HRS § 661-21(a)(2);
- Count Three: Reverse False Claims in Violation of the Hawaii FCA, HRS § 661-21(a)(7);
- Count Four: Conspiracy to Violate the Hawaii FCA, HRS § 661-21(a)(3);
- Count Five: False Claims in Violation of the Federal FCA, 31 U.S.C. § 3729(a)(1)(A);
- Count Six: False Records or Statements Material to False Claims in Violation of the Federal FCA, 31 U.S.C. § 3729(a)(1)(B);
- Count Seven: Reverse False Claims in Violation of the Federal FCA, 31 U.S.C. § 3729(a)(1)(G); and
- Count Eight: Conspiracy to Violate the Federal FCA, 31 U.S.C. § 3729(a)(1)(C).

ECF No. 51 at PageID ## 664-81

On June 30, 2020, Defendants filed their Motion to Dismiss. ECF No. 58. An Opposition and Reply were filed on September 14, 2020 and September 21, 2020, respectively. ECF Nos. 75, 79. The court held a hearing on the Motion to Dismiss on October 5, 2020 via video conference. ECF No. 83.

After the hearing, the parties filed supplemental memoranda addressing two issues regarding the claims-certification process and "reverse

claims" under 31 U.S.C. § 3729(a)(1)(G). ECF Nos. 84, 87. Meanwhile, the court granted the United States leave to file a Statement of Interest as a real party in interest, ECF No. 86, and the United States filed its Statement on October 30, 2020. ECF No. 90. Liberty filed a Response to the United States' Statement on November 13, 2020. ECF No. 93.

III. STANDARD OF REVIEW

Federal Rule of Civil Procedure 12(b)(6) permits a motion to dismiss for "failure to state a claim upon which relief can be granted[.]" A Rule 12(b)(6) dismissal is proper when there is either a "'lack of a cognizable legal theory or the absence of sufficient facts alleged.'" *UMG Recordings, Inc. v. Shelter Capital Partners, LLC*, 718 F.3d 1006, 1014 (9th Cir. 2013) (quoting *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990)).

Although a plaintiff need not identify the legal theories that are the basis of a pleading, *see Johnson v. City of Shelby, Mississippi*, 574 U.S. 10, 11 (2014) (per curiam), a plaintiff must nonetheless allege "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). This tenet—that the court must accept as true all of the allegations contained in the complaint—"is inapplicable to legal conclusions." *Id.*

Accordingly, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. (citing *Twombly*, 550 U.S. at 555); *see also Starr v. Baca*, 652 F.3d 1202, 1216 (9th Cir. 2011) ("[A]llegations in a complaint or counterclaim may not simply recite the elements of a cause of action, but must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively.").

Rather, "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678 (citing *Twombly*, 550 U.S. at 556). In other words, "the factual allegations that are taken as true must plausibly suggest an entitlement to relief, such that it is not unfair to require the opposing party to be subjected to the expense of discovery and continued litigation." *Starr*, 652 F.3d at 1216. Factual allegations that only permit the court to infer "the mere possibility of misconduct" do not show that the pleader is entitled to relief as required by Federal Rule of Civil Procedure 8. *Iqbal*, 556 U.S. at 679.

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IV. DISCUSSION

A. False Claims Act — Principles

Liberty first moves to dismiss Counts Five and Six, which allege that Liberty violated 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B).[5] Those sections impose liability against someone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B). Liability requires a "claim for payment or approval," where "[a] 'claim' includes direct requests for government payment as well as reimbursement requests made to the recipients of federal funds under a federal benefits program." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) ("*Campie*") (citing 31 U.S.C. § 3729(b)(2)(A)). That is, the "FCA attaches liability, not to the underlying fraudulent activity or to the government's wrongful

[5] Counts One and Two are essentially identical to Counts Five and Six, but are based on Hawaii law, HRS §§ 661-21(a)(1) and (a)(2). *See* ECF No. 51 at PageID ## 664-66. The court focuses on the federal claims because "the court applies the same analysis for liability under the federal and [Hawaii] FCA." *United States ex rel. Woodruff v. Hawaii Pac. Health*, 560 F. Supp. 2d 988, 997 n.7 (D. Haw. 2008) (citing *United States ex rel. Lockyer v. Hawaii Pac. Health*, 490 F. Supp. 2d 1062, 1072 (D. Haw. 2007)); *State v. One Love Ministries*, 142 Haw. 197, 202, 416 P.3d 918, 923 (Haw. Ct. App. 2018) (reasoning that because the Hawaii FCA "is patterned after the federal [FCA] . . . [Hawaii courts] therefore look to cases interpreting the [federal] FCA for guidance") (citations omitted).

payment, but to the 'claim for payment.'" *Cafasso v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995)) (square brackets omitted). "An actual false claim is 'the *sine qua non* of [an FCA] violation.'" *Id.* (quoting *United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 1002 (9th Cir. 2002)).

The Ninth Circuit has articulated four elements for a successful FCA cause of action under these provisions: "(1) a false statement or fraudulent course of conduct, (2) made with scienter, (3) that was material, causing (4) the government to pay out money or forfeit moneys due." *United States ex rel. Rose v. Stephens Inst.*, 909 F.3d 1012, 1017 (9th Cir. 2018) ("*Rose*") (quoting *United States ex rel. Hendow v. Univ. of Phoenix*, 461 F.3d 1166, 1174 (9th Cir. 2006) ("*Hendow*")). Courts "interpret the FCA broadly, in keeping with the Congress's intention 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1116 (9th Cir. 2020) (quoting *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968)), *petition for cert. filed* (U.S. Dec. 3, 2020) (No. 20-805). "As with all fraud allegations, a plaintiff must plead FCA claims 'with particularity' under Federal Rule of Civil Procedure 9(b)." *Id.* (quoting *Cafasso*, 637 F.3d at 1054).

1. Theories of "False or Fraudulent" Claims

The FCA gives rise to several different theories for determining whether a claim is "false or fraudulent." *See Hendow*, 461 F.3d at 1171. Initially, "[i]n an archetypal *qui tam* False Claims action, such as where a private company overcharges under a government contract, the claim for payment is itself literally false or fraudulent." *Id.* at 1170 (citation omitted). "A factually false claim is the prototypical FCA action, alleging an explicit lie in a claim for payment, such as an overstatement of the amount due." *United States ex rel. Garrett v. Kootenai Hosp. Dist.*, 2020 WL 3268277, at *4 (D. Idaho June 17, 2020) (citation and internal quotation marks omitted).

But the FCA "is not limited to such facially false or fraudulent claims for payment." *Hendow*, 461 F.3d at 1170. Rather, there are "two [other] doctrines that attach potential [FCA] liability to claims for payment that are not explicitly and/or independently false: (1) false certification (either express or implied); and (2) promissory fraud." *Id.* at 1171 (citation omitted). The case at bar involves the false certification theories.[6]

[6] The "promissory fraud" theory—which Relator has not sought to apply—"rather than specifically requiring a false statement of compliance with government regulations, is somewhat broader." *Hendow*, 461 F.3d at 1173. "It holds that liability will attach to each claim submitted to the government under a contract, when the contract or extension of government benefit was originally obtained through false statements or fraudulent conduct." *Id.* (citations omitted).

(continued . . .)

Under an express false certification theory, "'the entity seeking payment falsely certifies compliance with a law, rule or regulation as part of the process through which the claim for payment is submitted.'" *Rose*, 909 F.3d at 1017 (quoting *Ebeid ex rel. United States v. Lungwitz*, 616 F.3d 993, 998 (9th Cir. 2010) ("*Ebeid*")) (brackets omitted). In contrast, "implied false certification . . . 'occurs when an entity has *previously* undertaken to expressly comply with a law, rule, or regulation but does not, and that obligation is implicated by submitting a claim for payment even though a certification of compliance is not required in the process of submitting the claim.'" *Id.* (quoting *Ebeid*, 616 F.3d at 998) (brackets omitted).[7]

(. . . continued)
"[S]ubsequent claims are false because of an *original fraud* (whether a certification or otherwise)." *Id.*

[7] *Ebeid* recognized a theory of implied certification set forth in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), that was "'based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment.'" *Ebeid*, 616 F.3d at 996 (quoting *Mikes*, 274 F.3d at 699). "[U]nder *Ebeid*, a claim is false under an implied certification theory when it contains no express statement regarding compliance with a statute or regulation, but, *by the very fact that it has been submitted, falsely implies compliance* with any statutory or regulatory precondition to obtaining the requested government benefit." *United States ex rel. Lewis v. Cal. Inst. of Tech.*, 2019 WL 5595046, at *7 (C.D. Cal. Oct. 28, 2019) (citation and quotation marks omitted). *See also, e.g., United States v. San Bernardino Mountains Cmty. Hosp. Dist.*, 2018 WL 5264362, at *4 (C.D. Cal. June 14, 2018) ("[*Ebeid*] indirectly held that claims for payment, without more, can serve as a basis for implied certification liability."); *United States ex rel. Mateski v. Raytheon Co.*, 2017 WL 1954942, at *4 (C.D. Cal. Feb. 10, 2017) ("*Mateski*") (observing that a "relator need only show a scheme to defraud and the 'actual submission' of claims for payment.") (quoting *Ebeid*, 616 F.3d at 998-99) (brackets omitted).

In 2016, the Supreme Court in *Escobar* confirmed that, as a theory based on fraud,

> [an] implied certification theory can be a basis for [FCA] liability, at least where two conditions are satisfied: first, *the claim does not merely request payment*, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths.

Id. at 2001 (emphasis added). And—interpreting Ninth Circuit applications of *Escobar* after *Ebeid*—*Rose* subsequently held that, at least in the Ninth Circuit, an implied certification claim *must* satisfy both of *Escobar*'s conditions. *See Rose*, 909 F.3d at 1018 (discussing *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325, 332 (9th Cir. 2017) ("*Kelly*") and *Campie*, 862 F.3d at 901). That is, under *Rose*, an implied certification theory cannot—as *Ebeid* had earlier indicated—be based on "merely request[ing] payment." *Id.* (quoting *Escobar*, 136 S. Ct. at 2001). Rather, a defendant must (in addition to other elements) make "specific representations about the goods or services provided." *Rose*, 909 F.3d at 1018 (quoting *Escobar*, 136 S. Ct. at 2001). *See also, e.g.*, *Mateski*, 2017 WL 1954942, at *5 ("Nor did *Kelly* address *Ebeid*, which held that mere claims for payment could indeed form the basis for an FCA claim. Nonetheless, . . . [t]he most reasonable reading of *Kelly* is that mere claims for payment no longer suffice under

an implied certification theory; instead, the claims must contain specific representations about the defendant's performance.") (brackets, quotation marks, and citation omitted).

For example, in analyzing whether a mental health facility violated the FCA by submitting claims for Medicaid payment that failed to disclose that health providers were not properly licensed, *Escobar* reasoned that "submitting claims for payment using payment codes that corresponded to specific counseling services [and] . . . submitting Medicaid reimbursement claims by using National Provider Identification numbers corresponding to specific job titles" were sufficient representations about the services for which payment was sought. 136 S. Ct. at 2000. *See also, e.g.*, *Campie*, 862 F.3d at 902-03 (finding "specific representations about the goods or services provided," reasoning in part that "[j]ust as payment codes correspond to specific health services [in *Escobar*] . . . these drug names necessarily refer to specific drugs under the FDA's regulatory regime"); *United States ex rel. Beauchamp v. Academi Training Ctr., Inc.*, 220 F. Supp. 3d 676, 680 (E.D. Va. 2016) ("[T]he billing codes and job titles in the invoices, when viewed in conjunction with the . . . contract, did indeed specifically represent to the government that defendant's [personnel] had fulfilled the weapons qualifications requirement.") (citing *Escobar*).

Again, "'mere regulatory violations do not give rise to a viable FCA action.'" *Hendow*, 461 F.3d at 1171 (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) ("*Hopper*")) (brackets omitted). Instead, under these theories, "'it is the false *certification* of compliance which creates liability when certification is a prerequisite to obtaining a government benefit.'" *Id.* (quoting *Hopper*, 91 F.3d at 1266). Moreover, "[t]hat the theory of liability is commonly called 'false certification' is no indication that 'certification' is being used with technical precision . . . . So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement, or secret handshake; False Claims liability can attach." *Id.* at 1172.

2. Materiality

But not all false or fraudulent "certifications" create liability under the FCA. "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable[.]" *Escobar*, 136 S. Ct. at 1996. Under the FCA, "the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

Escobar characterizes the materiality standard as "rigorous," 136 S. Ct. at 1996, and "demanding," *id.* at 2003, because "[t]he [FCA] is not 'an all-purpose antifraud statute,' or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Id.* (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)).[8]

> A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance.

Id. Further, materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* (citations omitted). "Instead, [*Escobar*] explained, 'materiality looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation,' meaning the government." *Rose*, 909 F.3d at 1019 (quoting *Escobar*, 136 S. Ct. at 2002).

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[8] This rigorous and demanding *materiality* requirement "[does] not displace this court's obligation to construe broadly any theory of liability in which materiality can be proven." *Campie*, 862 F.3d at 899 n.4; *see Winter*, 953 F.3d at 1116 ("We interpret the FCA broadly, in keeping with the Congress's intention 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'") (quoting *Neifert-White Co.*, 390 U.S. at 232)). As *Escobar* reasoned, "'[i]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent,' concerns about fair notice and open-ended liability 'can be effectively addressed through strict enforcement of the [FCA's] materiality and scienter requirements.'" 136 S. Ct. at 2002 (quoting *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1270 (D.C. Cir. 2010)).

Rose reiterated "three scenarios [from *Escobar*] that may help courts determine the likely or actual behavior of the government[.]" *Id.* "First, 'proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2003). "Second, [*Escobar*] explained that, 'if the Government pays a particular claim in full despite its *actual knowledge* that certain requirements were violated, that is very strong evidence that those requirements are not material.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2003). And "[t]hird, 'if the Government regularly pays a particular type of claim in full despite *actual knowledge* that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.'" *Id.* (quoting *Escobar*, 136 S. Ct. at 2003-04).

Although courts "must examine the particular facts of each case," *id.* at 1020, courts nevertheless may still "dismiss [FCA] cases on a motion to dismiss or at summary judgment," based on a lack of materiality. *Escobar*, 136 S. Ct. at 2004 n.6. Courts may do so because the materiality standard "is a familiar and rigorous one," which must be pleaded "with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b)." *Id.* "For a false statement to be

material, a plaintiff must plausibly allege that the . . . violations are 'so central' to the claims that the government 'would not have paid [the] claims had it known of [the] violations.'" *Winter*, 953 F.3d at 1121 (quoting *Escobar*, 136 S. Ct. at 2004). Material misrepresentations "[go] to the very essence of the bargain," *Escobar*, 136 S. Ct. at 2003 n.5 (quotation marks and citation omitted), or are "at the core" of a program, *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 111 (1st Cir. 2016) (finding a misrepresentation about credentials "at the core" of the services so as be material upon *Escobar*'s remand from the Supreme Court); *see also United States ex rel. Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017) (observing that under *Escobar* "a material misrepresentation is one that goes 'to the very essence of the bargain.'") (citing *Escobar*, 136 S. Ct. at 2003 n.5).

B. Application of False Claims Act Principles—The FAC Fails to State a Claim Under a False Certification Theory

1. The FAC Sufficiently Alleges that Liberty Submitted "Claims for Payment"

Liberty first argues that the FAC fails to allege with particularity that false claims for payment were actually submitted. Liberty acknowledges that the FAC alleges that Liberty had deficient POCs and flow sheets, and improperly concealed deficiencies and filled in missing information after the fact. ECF No.

58-1 at PageID ## 719-20. It contends, however, that the FAC does not properly link such allegedly false or fraudulent activity to actual submissions of claims for payment. *See, e.g.*, *Kitsap Physicians Serv.*, 314 F.3d at 1002 ("It is not enough for [relator] to describe a [fraudulent] scheme in detail but then to allege simply and without any stated reason for [her] belief that claims requesting illegal payments must have been submitted.") (quotation marks and citation omitted). The court disagrees.

"[A] relator is not required to identify actual examples of submitted false claims; instead 'it is sufficient to allege particular details of the scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.'" *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1209 (9th Cir. 2019) (quoting *Ebeid*, 616 F.3d at 998-99) (internal quotation marks omitted). That is, "[a] relator is not required to identify representative examples of false claims to support every allegation, although the use of representative examples is one means of meeting the pleading obligation." *Id.* (citing *Ebeid*, 616 F.3d at 998).

Here, the FAC alleges in its first paragraph that "[a]lmost six years ago, Defendants began falsely billing the Government and knowingly retaining Government overpayments." ECF No. 51 at PageID # 602. The FAC alleges that

"[s]ince at least March 2013, Defendants have concealed pervasive noncompliance with regulations material to Government payment for" ESRD services. *Id.* It describes long-standing systemic deficiencies with Liberty's POC process for its ESRD patients, such as a lack of signatures, incomplete "stability determinations," and missing flow sheets, that violated various regulatory conditions for coverage for ESRD facilities. *See, e.g.*, *id.* at PageID ## 635-640. It provides a detailed specific example of the alleged problem with signatures. *Id.* at PageID # 657. And it alleges that Liberty took improper steps—such as backdating signatures and retroactively inserting other missing information in POCs—in an alleged effort to avoid having to return or refund "overpayments" that were obtained as a result of the regulatory violations. *See, e.g.*, ECF No. 51 at PageID # 603 ("[D]oing so could require [Liberty] to return up to millions of dollars of Government overpayments"); *id.* at PageID # 639 ("[T]hey would not report the noncompliance she uncovered because it would jeopardize certification and require them to return Government overpayments."); *id.* at PageID # 652 (alleging that noncompliance made it "difficult. . . for the Government to discover millions of dollars of overpayments it made for patients' thrice-weekly treatments going back at least as far as 2011"); *id.* at PageID # 661 ("[Liberty] owed the Government money for claims they had submitted that they now knew were false or ineligible for

payment."). Given these alleged "overpayments," it is obvious that Liberty must have first submitted "claims for payment" when the alleged problems with POCs existed.

The FAC also specifically alleges that "[b]efore March 2013, Defendants had billed Medicare and Medicaid for thrice-weekly treatments for over two hundred patients it was ineligible to bill for due to noncompliance." *Id.* at PageID # 607. The FAC alleges that, after a required state self-audit, "Defendants concealed noncompliance to unjustly receive Government money." *Id.* at PageID # 663. Later, the FAC alleges in various counts that Liberty "knowingly presented or caused to be presented false or fraudulent claims for payment for ESRD-related services," *id.* at PageID # 664, "falsified medical records to fraudulently obtain payments," *id.* at PageID # 667, "submit[ed] false progress reports and requests for payment certifying that Defendants were compliant with Medicare and Medicaid requirements," *id.* at PageID # 674, and the United States "paid and continue[s] to pay Defendants for the noncompliant dialysis services rendered." *Id.* at PageID # 676.

Combined, these allegations sufficiently allege "particular details of the scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *Godecke*, 937 F.3d at 1209. Even

if the FAC does not detail each claim that had a deficient POC, it easily alleges enough to infer that "claims for payment" were submitted. Whether the alleged regulatory violations are sufficient to create *liability* under an express or implied certification theory, and whether the violations are "material" under *Rose* and *Escobar*, are different questions, to which the court turns next.

2. No Allegations of an Express False Certification

Although the FAC pleads enough particular details to infer that Liberty submitted claims for payment with deficient POCs, the FAC fails to allege anywhere that any such claims falsely—and expressly—certified compliance with any "law, rule or regulation" regarding POCs (or with any alleged conditions of payment for ESRD services) "as part of the process through which the claim for payment is submitted." *Rose*, 909 F.3d at 1017. At most, the FAC alleges that in 2011, "Medicare switched to a bundled payment system for ESRD treatment," ECF No. 51 at PageID # 615, and the FAC therefore implies that claims after 2011 must have complied with that payment system. But nowhere does the FAC mention any specific certification that Liberty made regarding complying with payment requirements, much less that any certification was done as part of the claim-submission process.

Tacitly acknowledging this pleading deficiency, Relator asks the court to consider, or take judicial notice of, "Medicare claim forms, HCFA Form 1500 and UB04, stating certifications." ECF No. 75 at PageID # 892. Relator contends that these forms contain the necessary certifications. At the October 5, 2020 hearing, however, the court denied that request as improper because the FAC makes no mention of any type of claim form and makes no allegations regarding statements or certifications made during or prior to claims submission. *See, e.g.*, *United States v. Ritchie*, 342 F.3d 903, 908 (9th Cir. 2003) ("Even if a document is not attached to a complaint, it may be incorporated by reference into a complaint if the plaintiff refers extensively to the document or the document forms the basis of the plaintiff's claim."). Indeed, at the hearing, Liberty represented that it does not use a "Form 1500," and instead submits claims electronically with a "Form 837."[9] After the hearing, the court allowed the parties to address the claim submissions process in supplemental briefing, and the court discusses that process later in this Order when considering whether it would be futile for Relator to amend the FAC to allege these details.

[9] In its Statement of Interest, the United States describes the difference between a "Form 1500," which concerns claims by physicians, and a "Form 1450," which is relevant to claims by ESRD facilities. *See* ECF No. 90 at PageID # 1376-77. It also describes the electronic "Form 837I."

In short, the FAC fails to state a claim under an express false certification theory.

3. No Allegations of "Specific Representations" Made to the Government Under an Implied Certification Theory

Likewise, for an implied false certification theory, the FAC does not allege that—even if "a certification of compliance is not required in the process of submitting the claim"—Liberty had "*previously* undertaken to expressly comply with a law, rule, or regulation, and that obligation is implicated by submitting claims for payment." *Rose*, 909 F.3d at 1017 (quoting *Ebeid*, 616 F.3d at 998). Nor does the FAC allege facts establishing that Liberty made any "specific representations" about the ESRD services when making claims for payment. *Id.* at 1018 (quoting *Escobar*, 136 S. Ct. at 2001). At best, the FAC alleges that "[b]efore March 2013, [Liberty] had billed Medicare and Medicaid for thrice-weekly treatments for over two hundred patients it was ineligible to bill for due to noncompliance." ECF No. 51 at PageID # 607. But this allegation does not explain what Liberty "specifically represented," and is far from meeting the particularity standard.

Even though the FAC plausibly alleges with sufficient particularity that Liberty made claims for payment for ESRD services while having deficient POCs, it is not enough after *Escobar* and *Rose* merely to "point[] to

noncompliance with a law, rule, or regulation that is necessarily implicated in a defendant's claim for payment." *Rose*, 909 F.3d at 1017-18. That is, merely submitting a claim is insufficient to state a valid implied false certification theory, regardless of the particular allegations of fraud. Rather, "certification" and "specific representations" are also required. *See Hopper*, 91 F.3d at 1266 (reiterating that "it is the false *certification* of compliance which creates liability"); *Escobar*, 136 S. Ct. at 2001. The FAC fails to state a valid implied false certification theory.

As with an express false certification theory, Relator attempts to rely on details of the claim submission process that were not alleged (such as the written or electronic forms used for making claims for payment). And as with the express certification claims, the court considers that process later when addressing whether it would be futile to grant leave to amend an implied false certification claim.

4. The Alleged Regulatory Violations Were Not Material

Even if the FAC's allegations of billing for "thrice-weekly treatments" could be interpreted as sufficiently alleging that Liberty made "specific representations" and certifications about its billed ESRD services, the FAC still fails to state a claim because it does not plausibly allege the "materiality" of the

alleged regulatory violations. "Conditions for coverage" set forth in 42 C.F.R. Part 494 are necessary for an ESRD facility to be able to provide services and thus *qualify* to be paid, but they are not prerequisites for payment of claims. Although regulations allow for a facility's termination for failing to meet such conditions, the regulations also provide for "alternative sanctions" and allow payment to continue during a period of noncompliance. Moreover, the FAC does not allege particular facts indicating that the government declines to pay claims after being informed of violations of Part 494's conditions for coverage. The court next explains these points in more detail.

The FAC alleges that Liberty must comply with Part 494's "conditions for coverage" as conditions for receiving payment. In this regard, Relator relies heavily on 42 C.F.R. § 413.210(a), entitled "Qualifications for payment," which states: "[t]o qualify for *payment*, ESRD facilities must meet the conditions for coverage in part 494 of this chapter" (emphasis added). In turn, Part 494 sets forth "conditions for coverage for [ESRD] facilities," and defines the scope of the section: "[t]he provisions of [Part 494] establish the conditions for coverage of services under Medicare and are the basis for survey activities for the purpose of determining whether an ESRD facility's services may be covered." 42 C.F.R. § 494.1(b). Relator argues that deficiencies in Part 494's conditions are

"material" for purposes of the FCA because such deficiencies have "a natural tendency to influence, or [are] capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

But just because § 413.210(a) labels the conditions for coverage as "qualifications for *payment*" does not mean a violation of such conditions was material. *See Escobar*, 136 S. Ct. at 2001 (reasoning that "regulatory . . . requirements are not automatically material, even if they are labeled conditions of payment"). Rather, in context, § 413.210(a) and Part 494 establish requirements so that a facility *can* be paid—by definition, they are base level conditions for an ESRD facility to *qualify* to provide services (i.e., conditions for "coverage"). For purposes of Medicare, 42 C.F.R. § 488.1 specifically defines "conditions for coverage" as "mean[ing] the requirements suppliers must meet to *participate* in the Medicare program" (emphasis added). And even if that definition is not controlling, it certainly indicates a lack of materiality for FCA purposes. That context is apparent when examining Part 494 in detail.

Part 494 details 17 different "conditions for coverage" in four subparts: general provisions, patient safety, patient care, and administration. *See* 42 C.F.R. §§ 494.20 to 494.180. The conditions include requirements such as "Compliance with Federal State, and local laws and regulations," under which an

ESRD facility "must operate and furnish services in compliance with applicable . . . laws and regulations pertaining to licensure and any other relevant health and safety requirements," 42 C.F.R. § 494.20; and more basic "Governance" requirements, under which "[t]he ESRD facility is under the control of an identifiable governing body, or designated person(s) with full legal authority and responsibility for the governance and operation of the facility," 42 U.S.C. § 494.180. The conditions range from general requirements regarding building standards, 42 C.F.R. § 494.60 (requiring a "safe, functional, and comfortable treatment environment"), to specific guidance for particular renal procedures, *see, e.g.*, 42 C.F.R. § 494.50 (regarding "hemodialyzers and bloodlines").

Relator focuses on the POC conditions for coverage in 42 C.F.R. § 494.90, which provides in part that "the interdisciplinary team as defined at § 494.80 must develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the patient's needs[.]" Section 494.90(b) regarding "Implementation of the patient [POC]" specifies that a POC must "(i) Be completed by the interdisciplinary team, including the patient if the patient desires; and (ii) Be signed by team members, including the patient or the patient's designee[.]" The "interdisciplinary team" "consists of, at a minimum, the patient . . . a registered nurse, a physician treating the patient for ESRD, a

social worker, and a dietician." 42 C.F.R. § 494.80. But nothing in Part 494 provides that a failure to fulfill any condition is a ground to reject a claim for payment.

Ultimately, whether labeled as conditions of payment or of participation, a violation of Part 494's "conditions for coverage" for ESRD facilities does not mean that any particular claim for payment will not be reimbursed. A violation does not automatically exclude payment, much less necessarily exclude qualification for payment. In this regard, the court agrees with the analysis in *United States ex rel. Blundell v. Dialysis Clinic, Inc.*, 2011 WL 167246 (N.D.N.Y. Jan. 19, 2011), which concluded that "[t]he language in 42 C.F.R. § 494 clearly establishes [] condition[s] of participation, not prerequisites to receiving reimbursement from the government." *Id.* at *19. *Blundell* reasoned that "[i]n order to participate in the Medicare program, defendant, a dialysis center providing treatment for ESRD, must meet and adhere to these 'conditions' as standards for the quality of care." *Id.* (citation omitted); *cf. United States ex rel. Williams v. Renal Care Grp., Inc.*, 696 F.3d 518, 532 (6th Cir. 2012) ("The regulations set forth in the United States's complaint are conditions of participation, the violation of which do not lead to [FCA] liability."); *United States ex rel. Modglin v. DJO Global Inc.*, 114 F. Supp. 3d 993, 1019-20 (C.D. Cal. 2015)

(citing cases for the proposition that there is no FCA liability for violations of conditions of participation); *United States ex rel. Bierman v. Othofix Int'l, N.V.*, 113 F. Supp. 3d 414, 426 (D. Mass. 2015) (reasoning that "the [regulations] actually function only as conditions of participation and do not affect Medicare's payment decisions" thus they are "not material to the government's decision whether to pay a claim").

The FAC alleges that Relator believes, based on her own research and an October 2013 Medicare newsletter (and from conversations with a Liberty nurse manager), that Liberty was required to comply with Part 494's conditions for coverage to qualify for reimbursement, and might have to return overpayments for past violations. ECF No. 51 at PageID ## 643, 645, 662. And it is true that Medicare coverage may be terminated for failure to meet Part 494's conditions for coverage. *See* 42 C.F.R. § 488.604(a) ("Except as otherwise provided in this subpart, failure of a supplier of ESRD services to meet one or more of the conditions for coverage set forth in part 494 of this chapter will result in termination of Medicare coverage of the services furnished by the supplier.")[10]

[10] Even if § 488.604(a) includes seemingly mandatory language ("*will* result in termination"), the statutory language and structure includes many qualifications. *See id.* ("*Except as otherwise provided* in this subchapter . . .").

But alleging a possibility that the government *could* decline payments (or seek to recover past payments) does not necessarily establish a viable FCA claim. *See Escobar*, 136 S. Ct. at 2003 ("Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance."); *Kelly*, 846 F.3d at 334 ("[T]he possibility that the government would be entitled to refuse payment if it were aware of [defendant's] alleged violations is insufficient by itself to support a finding of materiality.").

Moreover, termination of participation under § 488.604(a) is subject to a formal administrative process consisting of notice and appeal rights. *See* 42 C.F.R. §§ 488.608 and 488.610. The regulations also provide for "alternative sanctions" in lieu of termination. *See* 42 C.F.R. § 488.606. Such sanctions include a reduction in payments, § 488.606(b)(2), and discontinuance of sanctions after a provider is in "substantial compliance," § 488.606(c). That is, a "defendant may continue to receive Medicare payments during a period of noncompliance [with Part 494]." *Blundell*, 2011 WL 167246, at *19.

These alternative-sanction provisions suggest that violations of conditions in Part 494 are not material for purposes of the FCA. *See Escobar*, 136 S. Ct. at 2003-04 ("[I]f the Government regularly pays a particular type of claim in

full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material."). *Escobar* specifically *rejected* a view of materiality that "any statutory, regulatory, or contractual violation is material so long as the defendant knows that the Government would be entitled to refuse payment were it aware of the violation." *Id.* at 2004. And persuasive authority reasons that a regulation having its own "independent sanction," such as a loss of billing privileges, indicates that the regulation is not a material condition of payment for FCA purposes. *See Williams*, 696 F.3d at 531-32; *see also Modglin*, 114 F. Supp. 3d at 1020 (dismissing FCA claim, reasoning in part that "[the regulation] does not concern reimbursement, and contains its own internal sanction—i.e., loss of billing privileges.") (citations omitted).

Further, the "added attenuation" between a regulatory violation and a payment decision—that is, between the possibility of losing qualifying ESRD status *after* an administrative process and only *then* being disqualified for payment—indicates that a Part 494 violation is not material for purposes of the FCA. *See San Bernardino Mountains*, 2018 WL 5264362, at *7. Here, like in *San Bernardino Mountains*, the FAC "alleges, at most, that [Part 494's conditions] are necessary to receive and maintain [ESRD facility] status, but fails to establish their

materiality to the payment of claims." *Id.* at *8. "Relator does not establish a connection between payment and noncompliance." *Id.* *See also, e.g.*, *Hopper*, 588 F.3d at 1330 (finding an FCA complaint deficient for failure to "link the alleged false statements to the government's decision to pay false claims"). Put differently, Relator did not "plausibly allege that the [Part 494 violations] are 'so central' to the claims [for ESRD services] that the government 'would not have paid these claims had it known of these violations.'" *Winter*, 953 F.3d at 1121 (quoting *Escobar*, 136 S. Ct. at 2004). They do not go "to the very essence of the bargain." *Escobar*, 136 S. Ct. at 2003 n.5.

Finally, the FAC fails to allege any specific facts regarding "the likely or actual behavior" of the government after receiving claims with deficient POC documentation. *Id.* at 2002. The FAC fails to allege with any particularity any situations where "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with [Part 494's conditions." *Id.* at 2003. Indeed, the FAC alleges the opposite—in this case, the government continued to pay claims even after being notified of POC deficiencies. As Liberty argues, the FAC alleges that Relator reported the alleged deficiencies to federal and state government agencies, ECF No. 51 at PageID ## 636, 647, but the FAC does not allege that the government stopped paying claims as a result. Instead, the State of

Hawaii, when it became aware of deficiencies, ordered a "self audit" of all POCs. *Id.* at PageID # 640-41. Nothing in the FAC alleges that the federal government subsequently refused to pay claims or required repayment of past claims. This is so even after—as the FAC acknowledges—Relator filed her previous *qui tam* action (*Cabico*, Civ. No. 15-309 JMS-RLP) in August 2015 based on the same allegations of violations of Part 494, and even after that complaint was unsealed on October 24, 2016 and dismissed without prejudice on May 23, 2017. *See* ECF No. 51 at PageID # 609. Rather than alleging materiality with particularity, these allegations suggest that the violations are *not* material under the FCA. *See Escobar*, 136 S. Ct. at 2003 ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.").

In short, the FAC also fails to state an FCA claim given a lack of materiality. *See Escobar*, 136 S. Ct. at 2002-03. And because the federal claims fail, the corresponding Hawaii claims also fail. *See One Love Ministries*, 142 Haw. at 202, 416 P.3d at 923.

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C. Conspiracy Claim Under Both 31 U.S.C. § 3729(a)(1)(C) and HRS § 661-21(a)(8) Fail

Counts Four and Eight allege conspiracy to violate the FCA in violation of the Hawaii FCA and federal FCA.[11] These Counts fail to state claims because the court has found no violations of the FCA in the first instance—there can be no conspiracy to violate the FCA if no false and material claims were submitted. *See, e.g., Woodruff*, 560 F. Supp. 2d at 1004 ("Because the court concludes that Defendants did not submit false claims . . . Plaintiffs' conspiracy claim fails. Absent evidence of a false claim as alleged, Defendants did not conspire to have a false claim paid by the United States.") (citations omitted); *United States ex rel. Petras v. Simparel, Inc.*, 857 F.3d 497, 507 & n.53 (3d Cir. 2017) ("Our explanation of why the District Court was correct in dismissing the FCA claim applies with equal force to the dismissal of [relator's] conspiracy claim.") (citing *Pencheng Si v. Laogai Research Found.*, 71 F. Supp. 3d 73, 89 (D.D.C. 2014) ("[T]here can be no liability for conspiracy where there is no underlying violation of the FCA.")).

[11] Count Four alleges a conspiracy claim based on a superseded version of the Hawaii FCA, HRS § 661-21(a)(3) (2011). *See* ECF No. 51 at PageID # 670. Section 661-21(a)(3) was amended in 2012, and replaced by HRS § 661-21(a)(8). *See* 2012 Haw. Sess. L. Act 294, § 6 (July 9, 2012). The court construes the FAC as asserting a claim under § 661-21(a)(8).

In any event, the conspiracy claims also fail because, at best, the FAC alleges that the Defendants are all affiliated with one another. *See* ECF No. 51 at PageID # 610 ("Defendants Liberty Dialysis-Hawaii LLC ('Liberty') . . . Liberty Dialysis-North Hawaii LLC . . ., and Fresensius (sic) Medical Care Holdings, Inc. . . . jointly own, operate and manage 19 dialysis clinics . . . including but not limited to Defendants' Siemsen, Sullivan and Home Program units") and PageID # 611 ("Liberty is a subsidiary of Fresenius."). The conspiracy claims are thus barred by the intracorporate conspiracy doctrine, under which "as a matter of law, a corporation cannot conspire with its own employees or agents." *United States ex rel. Lewis v. Honolulu Cmty. Action Program, Inc.*, 2018 WL 4374163, at *3 n.3 (D. Haw. Sept. 13, 2018) (quoting *Hoefer v. Fluor Daniel, Inc.*, 92 F. Supp. 2d 1055, 1057 (C.D. Cal. 2000)).

In *Lewis*, this court applied the intracorporate conspiracy doctrine to dismiss conspiracy claims under the FCA, as well as conspiracy claims under the Hawaii FCA. *Id.* at *3 & n.3. The court agrees with the many cases that have barred conspiracy claims under the FCA between a parent and its subsidiaries. *See, e.g.*, *United States ex rel. Fisher v. IASIS Healthcare LLC*, 2016 WL 6610675, at *15-16 (D. Ariz. Nov. 9, 2016) (finding the doctrine bars conspiracy claims between parent company and subsidiary entities); *United States ex rel. Campie v.*

Gilead Sciences, Inc., 2015 WL 106255, at *15 (N.D. Cal. Jan. 7, 2015) (finding the doctrine bars an FCA conspiracy claim between a parent corporation and a wholly-owned subsidiary); *United States ex rel. Ruhe v. Masimo Corp.*, 929 F. Supp. 2d 1033, 1038 (C.D. Cal. 2012) ("Contrary to Relators' assertion, this doctrine applies to conspiracy claims outside of antitrust, where it was originally developed, and has in fact been applied by several federal courts to claims under the FCA.") (citations omitted).

In short, Counts Four and Eight are DISMISSED.

D. "Reverse" False Claims Under Both 31 U.S.C. § 3729(a)(1)(G) and HRS § 661-21(a)(6) Fail

Counts Three and Seven allege a theory of "reverse" false claims under the Hawaii FCA and federal FCA.[12] The reverse false claims provisions are violated if someone "knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). The FCA defines an "obligation" as "an established

[12] As with Count Four, Count Three alleges a reverse false claim violation based on a superseded version of the Hawaii FCA, HRS § 661-21(a)(7) (2011). That section was replaced by HRS § 661-21(a)(6) in 2012, and is identical to 31 U.S.C. § 3729(a)(1)(G). *See* 2012 Haw. Sess. L. Act 294, § 6 (July 9, 2012). The court construes the FAC as making a claim under § 661-21(a)(6).

duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." 31 U.S.C. § 3729(b)(3) (emphasis added).

Under 42 U.S.C. § 1320a-7k(d), a person receiving an overpayment must report and return the overpayment "by the later of (A) the date which is 60 days after the date on which the overpayment was identified; or (B) the date any corresponding cost report is due, if applicable." *Id.* § 1320a-7k(d)(2). Any overpayment retained after that deadline is an "obligation" for purposed of 31 U.S.C. § 3729. *See* 42 U.S.C. § 1320a-7k(d)(3). The statute defines an "overpayment" as "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled[.]" 42 U.S.C. § 1320a-7k(d)(4)(B).

The FAC alleges that Liberty violated these provisions by improperly retaining "overpayments" consisting of payments the government previously made for claims that contained violations of Part 494's conditions for coverage, including deficient POCs and flowsheets for home care. *See, e.g.*, ECF No. 51 at PageID ## 603, 639, 652, 661. It alleges that Defendants knew they had received such overpayments by at least March 2013 when the State imposed its audit

because of POC deficiencies. ECF No. 51 at PageID ## 669, 677. And it alleges that the overpayments became "obligations" after they were not reported and not repaid under 42 U.S.C. § 1320a-7k(d)(3). *Id.* at PageID # 677.

These reverse false claims theories fail, however, because the court has determined that Liberty did not make false or fraudulent claims for payment in the first place—even if claims for payment were submitted with deficient POCs (or other violations of Part 494's conditions for coverage), FCA liability is not implicated under an express or implied false certification basis, and the violations would not have been material. Thus, there were no "overpayments," and consequently no "obligations" for Defendants to return under 31 U.S.C. §§ 3729(a)(1)(G) and 3729(b)(3).

Furthermore, the court agrees with the substantial authority holding that an actionable reverse false claim cannot be based on a defendant's failure to *refund* the *same* payment that was obtained by an actionable false claim. Such a claim under § 3729(a)(1)(G) would be redundant of the original claim. *See, e.g.*, *United States v. Kinetic Concepts, Inc.*, 2017 WL 2713730, at *13 (C.D. Cal. Mar. 6, 2017) ("In cases where a plaintiff alleges a reverse false claim by claiming that the defendant fraudulently overcharged the government, court have consistently dismissed the claim as redundant of false statement and presentment claims.")

(citation omitted); *United States ex rel. Behnke v. CVS Caremark Corp.*, 2020 WL 1953626, at *10 (E.D. Pa. Apr. 23, 2020) ("[I]n order to plausibly allege a violation of § 3729(a)(1)(G), a plaintiff cannot merely recast his false statement claim by essentially alleging that the defendant failed to refund the false claims that the government paid.") (quotation marks, brackets, and citation omitted); *United States ex rel. Martino-Fleming v. S. Bay Mental Health Ctr.*, 2018 WL 4539684, at *6 (D. Mass. Sept. 21, 2018) ("Nor can reverse-FCA liability be premised solely on the same conduct that gives rise to traditional presentment or false-statement claims.") (citations omitted); *Laogai Research Found.*, 71 F. Supp. 3d at 97 (rejecting argument that concealment of fraudulent activity resulted in reverse false claim liability because "by this logic, just about *any* traditional false statement or presentment action would give rise to a reverse false claim action; after all, presumably any false statement action under sections 3729(a)(1)(A) or 3729(a)(1)(B) could theoretically trigger an obligation to repay the fraudulently obtained money") (citation omitted).

Although it is possible for a complaint to allege both false statement claims and reverse claims, recovery under a reverse claims theory must be based on "an obligation that arose independent of the affirmative false claims themselves." *United States ex rel. Schaengold v. Mem'l Health, Inc.*, 2014 WL

6908856, at *21 (S.D. Ga. Dec. 8, 2014). There is no such independent basis alleged here. Rather, the reverse claims here are based solely on "overpayments" that are the same amounts the government allegedly paid to Liberty in the first place. And even if a reverse theory could be pled in the alternative, here it fails for the same reason the false certification claims fail.

For these reasons, Counts Three and Seven are DISMISSED.

E. Statute of Limitations

Liberty also argues that the FAC is barred by the FCA's statute of limitations. Under 31 U.S.C. § 3731(b):

> A civil action under section 3730 may not be brought—
>
> (1) more than 6 years after the date on which the violation of section 3729 is committed, or
>
> (2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,
>
> whichever occurs last.

Under the six-year prong, any violations that occurred before February 1, 2013 would appear to be barred. The FAC alleges that false claims were submitted "before March 2013," and thus at least some of the alleged

violations would not be time-barred. The FAC also alleges that Liberty's "noncompliance with the [POC] requirements is ongoing." ECF No. 51 at PageID # 663. Accordingly, even if much relief might be time-barred, given these allegations, the court would not dismiss the FAC on statute of limitations grounds at this motion-to-dismiss stage. But because the court dismisses the FAC for other reasons, the court need not address whether the FAC is time-barred, in whole or in part.

F. Leave to Amend Would be Futile

As discussed earlier, in attempting to establish that Liberty had expressly or impliedly certified compliance with applicable regulations for purposes of a false certification claim, Relator had sought to rely on an unpled theory that sufficient statements were made on Centers for Medicare and Medicaid Services ("CMS") "Forms 1500 or UB04." ECF No. 75 at PageID # 892. In supplemental briefing, the parties (including the United States as a real party in interest) addressed the particulars of the claim submission process, *see* ECF Nos. 84, 87, 93, and the court now considers those submissions in determining whether it would be futile to grant Relator leave to amend the FAC to include particulars of that claim submission process.

Supplemental briefing establishes that a dialysis facility may submit a CMS Form 1450 "or its electronic equivalent, known as the 837I Format" to obtain Medicare reimbursement for dialysis services. ECF No. 90 at PageID # 1376. According to the United States' Statement (and as undisputed by anyone), providers certify on the CMS Form 1450, among other things, that "submission of this claim constitutes certification that the billing information as shown on the face hereof is true, accurate and complete," and "that the submitter did not knowingly or recklessly disregard or misrepresent or conceal material facts." *Id.* at PageID # 1377 (citations omitted). The United States maintains that "[t]he electronic claim submissions process is aligned with the paper claim forms; all relevant information contained on the paper form is likewise replicated on this electronic claim." *Id.* (citation omitted). The claims, "whether in hardcopy or through the 837I process, includes the patient's name and the dates that services were provided." *Id.* at PageID # 1378. And claims include specific codes that identify and describe the specific services for which reimbursement is sought, along with a national provider identifier corresponding to the ESRD facility. *Id.* [13]

[13] Relator agrees that the 837I form uses a series of codes, and she also discusses general certifications used in provider agreements, such as those explained by the United States. *See* ECF No. 84 at PageID ## 1124-25. Similarly, Liberty explains in detail the meaning of specific codes in the 837I process. *See* ECF No. ECF No. 87 at PageID ## 1310-11; ECF No. 87-2 at PageID ## 1331-33. Thus, the parties essentially agree on the type of allegations that could be (continued . . .)

The United States also explains that dialysis facilities must submit a Form CMS-855A when enrolling or at other times. ECF No. 90 at PageID # 1375. That form requires a provider to certify:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.
> . . . .
> I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

Id. at PageID ## 1375-76. A certification section of that form "legally and financially binds the provider to all of the laws, regulations, and program instructions of the Medicare program." *Id.* at PageID # 1376.

But even if the FAC was amended to include these details about the claims submission process, a second amended complaint would still fail to state an

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(. . . continued)
made in a second amended complaint, although the parties dispute the significance of such allegations (and the United States took no position on whether the facts would be sufficient to state viable FCA claims, and limited its discussion to the claims process and the legal framework, *see* ECF No. 90).

express false certification claim. Nothing indicates that, in this process, Liberty would have "expressly certified compliance with a law, rule or regulation" regarding POCs "as part of the process through which the claim for payment is submitted." *Rose*, 909 F.3d at 1017 (quoting *Ebeid*, 616 F.3d at 998). Relator appears to admit that no such express certification is made with Form 837I, ECF No. 84 at PageID # 1127, arguing instead that certification must occur in other ways under an implied certification theory.

And for purposes of any false certification theory—express or implied—ample case law reasons that such general statements of compliance with all laws are insufficient to state a viable FCA cause of action. *See Escobar*, 136 S. Ct. at 2004 ("The [FCA] does not adopt such an extraordinarily expansive view of liability."); *United States ex rel. Porter v. Magnolia Health Plan*, 810 F. App'x 237, 242 (5th Cir. 2020) (affirming the district court's conclusion that a contract that "contain[ed] broad boilerplate language generally requiring a contractor to follow all laws, which is the same type of language *Escobar* found too general to support" lacked materiality under the FCA); *United States ex rel. Sirls v. Kindred Healthcare, Inc.*, 469 F. Supp 3d 431, 449-50 (E.D. Penn. 2020) ("Relator's references to boilerplate language conditioning payment under Medicare and Medicaid on compliance with all laws and regulations are not sufficient to satisfy

the demanding standard established in *Escobar*.") (citing *Porter*); *United States ex rel. Conner v. Salina Reg. Health Ctr., Inc.*, 543 F.3d 1211, 1219-20 (10th Cir. 2008) ("*Conner*") (holding that certification compliance with "the laws and regulations regarding the provision of health care services" was too general to support a false certification claim, reasoning in part that "[w]here a contractor participates in a certain government program in order to perform the services for which payments are eventually made—in this case, Medicare—courts are careful to distinguish between conditions of program *participation* and conditions of *payment*") (citations omitted); *United States ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 315 (S.D.N.Y. 2011) ("General certifications of compliance with the law are insufficient.") (citing *Conner*).

Moreover, even if Relator alleged that Liberty submitted claims using specific codes for particular services—similar to codes that *Escobar* found sufficient to constitute "specific representations"—those submissions would not constitute relevant representations (or misrepresentations) because none of the codes implicated POCs. As Liberty points out, "[t]here were no codes linked to creating or maintaining supporting documentation, such as POCs, or to any other task which was not a direct service/item furnished to a patient for the treatment of ESRD." ECF No. 87 at PageID # 1311; *see also* ECF No. 87-2 at PageID # 1333

("None of the items or services billed on Liberty's form 837I transaction sets includes plans of care."). Rather, at most, Liberty "specifically represented" in submitted codes that it provided particular items or services. Under Medicare's "bundled payment" system in use since 2011, payment covers "(a) Renal dialysis services as defined in [42 C.F.R.] § 413.171; and (b) Home dialysis services, support and equipment as identified in [42 C.F.R.] § 410.52." 42 C.F.R. § 413.217 (entitled "Items and services included in the ESRD prospective payment system").[14] In turn, none of those core services in sections 413.171[15] or 410.52[16]

[14] *See also* 42 C.F.R. § 413.210(b) ("CMS will not pay any entity or supplier other than the ESRD facility for covered items and services furnished to a Medicare beneficiary. The ESRD facility must furnish all covered items and services defined in § 413.217 of this part either directly or under arrangements.").

[15] 42 C.F.R. § 413.171 defines "Renal dialysis services" as:

> Effective January 1, 2011, the following items and services are considered "renal dialysis services," and paid under the ESRD prospective payment system under section 1881(b)(14) of the Act:
>
> (1) Items and services included in the composite rate for renal dialysis services as of December 31, 2010;
>
> (2) Erythropoiesis stimulating agents and any oral form of such agents that are furnished to individuals for the treatment of ESRD;
>
> (3) Other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was (prior to January 1, 2011) made separately under Title XVIII of the Act (including drugs and biologicals with only an oral form),

(continued . . .)

include POCs. That is, as Liberty states, "POCs are not covered services under § 413.217 and are not an item reimbursable under the bundled-payment system." ECF No. 87 at PageID # 1313. "POCs document the treatment plan; they are not the treatment itself." *Id*. at PageID # 1316. *Cf. Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1109 (11th Cir. 2020) ("We conclude that the lack of [comprehensive] care plans fails to establish Medicaid fraud [because] the relator failed to connect the absence of care plans to specific representations regarding the services provided. Moreover, the relator did not allege . . . any deficiencies in the Medicaid services provided.").

Finally, even if a prior certification were enough and the codes could plausibly be interpreted as making specific representations about services, an

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(. . . continued)

> (4) Diagnostic laboratory tests and other items and services not described in paragraph (1) of this definition that are furnished to individuals for the treatment of ESRD.
>
> (5) Renal dialysis services do not include those services that are not essential for the delivery of maintenance dialysis.

[16] 42 C.F.R. § 410.52(a) provides that "Medicare Part B pays for the following services, supplies, and equipment furnished to an ESRD patient in his or her home:" "(3) Home dialysis support services furnished by an approved ESRD facility, including periodic monitoring of the patient's home adaptation, emergency visits by qualified provider or facility personnel, any of the tests specified in paragraphs (b) through (d) of § 410.50, personnel costs associated with the installation and maintenance of dialysis equipment, testing and appropriate treatment of water, and ordering of supplies on an ongoing basis."

implied false certification theory would still fail for lack of materiality.[17] The court's extensive previous analysis regarding a lack of materiality for Part 494's conditions for coverage as to the FAC would still apply to a further amended complaint. Again, Part 494's conditions are requirements for *participation*, not payment. They are not "so central" to the claims Liberty made for ESRD services that Medicaid or Medicare would not have paid the claims. *Winter*, 953 F.3d at 1121. They do not go to "the very essence of the bargain." *Escobar*, 136 S. Ct. at 2003 n.5. Even if POC deficiencies could lead to termination—after a regulatory notice and administrative appeal process—of Liberty's qualifications to provide ESRD services, such an "added attenuation" between regulatory violations and a payment denial indicates that a violation is not material for FCA purposes. *See San Bernardino Mountains*, 2018 WL 5264362, at *7.

For all those reasons, because further amendment would be futile, the court denies Relator's request for leave to amend. *See* ECF No. 75 at PageID # 913. The dismissal is with prejudice. *See, e.g.*, *Parents for Privacy v. Barr*, 949

[17] Put differently, at the second prong of *Escobar*'s implied false certification test, it would not be a "misleading half-truth" to fail to disclose problems with the POC process because POC violations are not "material" conditions for payment. *See Rose*, 909 F.3d at 1018 (reiterating the second condition of an implied certification theory under *Escobar* as "the defendant's failure to disclose noncompliance with *material* . . . regulatory. . . requirements makes those representations misleading half-truths") (quoting *Escobar*, 136 S. Ct. at 2001) (emphasis added).

F.3d 1210, 1221 (9th Cir. 2020) ("A district court acts within its discretion to deny leave to amend when amendment would be futile.") (quotation marks and citation omitted).

V. CONCLUSION

Relator alleges troublesome facts sounding in fraud regarding noncompliance with POC requirements. But, although the court does not condone such violations, they are not the basis for a claim under the False Claims Act. For the foregoing reasons, the court GRANTS Defendants' Motion to Dismiss in full. Leave to amend would be futile. The Clerk of Court shall close the case file.

IT IS SO ORDERED.

DATED: Honolulu, Hawaii, January 12, 2021.

/s/ J. Michael Seabright
J. Michael Seabright
Chief United States District Judge